AUG 4 2000

K001614

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Stryker Trauma Pelvic Set

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 201-825-4900
Contact Person:	Mary-Catherine Dillon Regulatory Affairs Team Member
Date Summary Prepared:	March 23, 2000

Device Identification

Proprietary Name:	Stryker Trauma Pelvic Set
Common Name:	Pelvic Set
Classification Name and Reference:	Plate, Fixation, Bone 21 CFR §888.3030

Predicate Device Identification

The Stryker Trauma Pelvic Set is substantially equivalent to the Synthes Pelvic Implant Set.

Device Description

The Stryker Trauma Pelvic Set consists of 88mm radius and 108mm radius curved plates, straight pelvic plates, straight acetabulum plates, and symphysis-pubis plates. All curves and straight plate components are available in 10.5mm widths and 2.5mm thicknesses. The symphysis-pubis plates are also available in a 12.5mm width and 3.2mm thickness. The subject components vary in length from 22.5mm to 474.5mm. The system also includes 3.5mm diameter and 4.5mm diameter screws. All devices in the system are provided both sterile and non-sterile.

Intended Use

The Stryker Trauma Pelvic Set is indicated for:

- Fractures of the acetabulum, sacrum, illium, and entire pelvic ring
- Revision surgery of pseoduarthroses, non-unions and mal-unions

- Osteonomies
- Arthrodeses
- Sacroilic joint dislocations
- Symphysis pubis disruptures

Materials

The subject components are manufactured from stainless steel which conforms to ASTM F-138.

Statement of Technological Comparison

The subject components of the Stryker Trauma Pelvic Set are substantially equivalent in design and intended use to the predicate device offered by Synthes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Ms. Mary-Catherine Dillon
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K001614
Trade Name: Stryker Trauma Pelvic Set
Regulatory Class: II
Product Code: KTW
Dated: May 24, 2000
Received: May 25, 2000

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachman.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001614

Device Name: Stryker Trauma Pelvic Set

Indications For Use:

The Stryker Trauma Pelvic Set is indicated for:

- Fractures of the acetabulum, sacrum, illium, and entire pelvic ring
- Revision surgery of pseoduarthroses, non-unions and mal-unions
- Osteonomies
- Arthrodeses
- Sacroilic joint dislocations
- Symphysis pubis disruptures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001614

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)